REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1, 3 and 5-11 are pending in this application. By this Amendment, claim 1 is amended and claim 8 is cancelled. No new matter is added.

Entry of the amendments is proper under 37 CFR §1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (as the amendments address issues previously discussed throughout prosecution); (c) do not present any additional claims without cancelling a corresponding number of finally rejected claims; and (d) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

I. Information Disclosure Statement

The Examiner asserts that the Information Disclosure Statements filed on February 26, 2008 and March 6, 2008 fail to comply with the provisions of 37 CFR 1.97 and 1.98, and MPEP § 609, because there is no translation of EP 0243408 and there was no supplemental search report submitted. However, Applicants submitted the Supplementary Partial European Search Report, issued July 31, 2008, with the Information Disclosure Statement filed on February 26, 2008, and a corrected PTO-1449 form on March 6, 2008 to correct item CA and properly list the Supplementary Partial European Search Report.

Applicants submit herewith another copy of the Supplementary Partial European Search Report, which cites EP 0243408. Accordingly, Applicants respectfully request express consideration of the references cited on the PTO-1449 submitted March 6, 2008.

II. Claim Rejection Under 35 U.S.C. § 102

The Examiner rejects claims 1, 3 and 8 under 35 U.S.C. § 102(b) as being anticipated by Ogawa et al. (U.S. Patent No. 4,910,225) ("Ogawa"). By this Amendment, claim 8 is cancelled, rendering its rejection moot. As to claims 1 and 3, Applicants respectfully traverse the rejection.

The Examiner states that the organic amine was expanded to include ethylenediamine. By this Amendment, claim 1 is amended to delete "ethylenediamine" and "triethylenediamine." Accordingly, the organic amine of claim 1 is limited to an amino acid, an alkanolamine, a piperazine and an aminoalkylsulfonic acid.

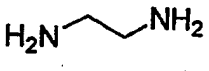
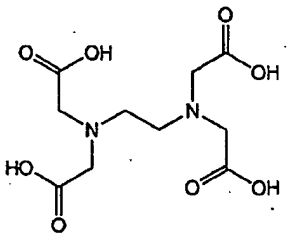
Ogawa describes an ophthalmic composition for inflammatory eye disease. However, Ogawa does not teach an aqueous eye drop comprising the combination of (i) 2-amino-3-(4-bromobenzoyl)phenylacetic acid (i.e., bromfenac) or its pharmacologically acceptable salt or a hydrate thereof, and (ii) at least one organic amine selected from the group consisting of an amino acid, an alkanolamine, a piperazine and an aminoalkylsulfonic acid, as claimed.

Therefore, Ogawa does not disclose each and every feature of claim 1, and thus does not anticipate claim 1. Claim 3 depends from claim 1, and thus is also not anticipated by Ogawa. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Moreover, Applicants wish to point out that Ogawa describes at column 4, lines 33-34, sodium edetate as one example of a chelating agent that may be added to the ophthalmic

composition. However, sodium edetate is different in structure and physicochemical properties from ethylenediamine and trimethylenediamine, and is, therefore, a completely different product from ethylenediamine and trimethylenediamine. See e.g., the table shown below, and The Merck Index, Thirteenth Edition, items 3829 and 3543 (enclosed).

Table

	Ethylenediamine	Sodium edetate
Structure		 (two -OH groups are -ONa)
Molecular weight	60.1	336.21
M.P.	8.5°C	252°C
B.P.	116-117°C	---
LD_{50}(rat)	1.16g/kg	2g/kg
pH	strong base	weak acid
Chelating action	found	found

Although ethylenediamine and sodium edetate exert chelating action, ethylenediamine is liquid at room temperature, whereas the melting point of sodium edetate is 252°C, which is very high.

Moreover, in an aqueous solution, an ethylenediamine solution is strongly basic, and a sodium edetate solution is slightly acidic. Plus, their physicochemical properties are different

from each other.

With regard to the LD_{50} value, which represents the safety to animals, the LD_{50} (in a rat) of sodium edetate is about twice as much as that of ethylenediamine. Therefore, it is clear that the reaction in the living body differs between sodium edetate and ethylenediamine as well.

Nevertheless, ethylenediamine and trimethylenediamine are deleted from claim 1, because these amines show the same chelating action as sodium edetate.

Therefore, it is clear that "one organic amine selected from the group consisting of an amino acid, an alkanolamine, a piperazine and an aminoalkylsulfonic acid," as recited in claim 1, is quite different from sodium edentate.

II. Claim Rejection Under 35 U.S.C. § 103

The Examiner rejects claims 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Ogawa as applied to claims 1, 3 and 8 above, in view of Kato et al. (U.S. Patent No. 5,945,121) ("Kato"). Applicants respectfully traverse the rejection.

The Examiner acknowledges that Ogawa does not teach the incorporation of taurine (aminosulfonic acid), but asserts that Kato teaches that taurine is effective in the treatment of dry eye, and other inflammatory conditions. Thus, the Examiner asserts that it would have been obvious to combine Ogawa, which describes an anti-inflammatory ingredient, with Kato, which describes an active ingredient for treating dry eye. Applicants respectfully disagree.

Kato teaches liposome eye drops where taurine is encapsulated in a liposome of the liposome eye drops to enhance retentivity on the corneal surface for treating corneal injury and corneal damages. See Kato at column 1, lines 31-32, column 2, lines 37-39, and column 6, lines 1-2 and 8-10.

On the other hand, in the claimed invention, the effect of enhancing the treatment of inflammatory disease of the eye is achieved by mixing taurine with bromfenac, without the need for using a medium such as a liposome. That is, in the claimed invention, a drug carrier, such as a liposome is not necessary.

Furthermore, Applicants have surprisingly and unexpectedly found that the use of aminoethylsulfonic acid (taurine) in the eye drop of the claimed method has a higher inhibition rate over drops without taurine. These surprising results are clearly shown in Experimental Example 2 on page 23, line 12 to page 26, line 2 of the specification, and Table 5.

As Experimental Example 2 shows, the inhibition rate of the formulation in which no taurine was added (Formulation 4) was 0.3% at 24 hours after the puncture, whereas the inhibition rate of Formulation 5 containing 0.5% taurine was 25.5%, and the inhibition rate of Formulation 6 containing 1.0 % taurine was 73.9%. Thus, it is quite clear from this experimental data that the claimed method shows superior and unexpected results for the treatment of inflammation.

Thus, even if Ogawa and Kato were combined, one of ordinary skill in the art would not have expected the surprising results of improving the treatment of inflammation with a formulation including taurine.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 3, 5-7 and 9-11 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Enclosures: The Merck Index, 13th Ed., pages 620 and 675
Supplementary Partial European Search Report

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